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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,464	03/13/2001	Thomas M. Kundig	05184.00002	8772

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EXAMINER	
JAMROZ, MARGARET E	

ART UNIT	PAPER NUMBER
1644	5

DATE MAILED: 04/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/804,464	KUNDIG ET AL.	
	Examiner	Art Unit	
	Margaret E Jamroz	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *restriction election facsimile* .

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating papers for this application, all further correspondence regarding this application should be directed to Megan Jamroz in Art Unit 1644, Technology Center 1600.

Restriction Requirement

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

In view of the delays in the mail at the present time, the office strongly encourages faxing responses.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1. Claims 1-10, 14, and 16-42, drawn to a method of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual, wherein the allergen is venom; classified in Class 424, subclass 275.1.

2. Claims 1-10, 12, 14, and 16-42, drawn to a method of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual, wherein the allergen is pollen; classified in Class 424, subclass 275.1.

3. Claims 1-10, 14, and 16-42, drawn to a method of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual, wherein the allergen is mold; classified in Class 424, subclass 275.1.

4. Claims 1-10, 14, and 16-42, drawn to a method of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual, wherein the allergen is an anesthetic; classified in Class 424, subclass 275.1.

5. Claims 1-10, 14, and 16-42, drawn to a method of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual, wherein the allergen is serum; classified in Class 424, subclass 275.1.

6. Claims 1-10, 14, and 16-42, drawn to a method of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual, wherein the allergen is drugs; classified in Class 424, subclass 275.1.

7. Claims 1-10, 13-14, and 16-42, drawn to a method of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual, wherein the allergen is an animals, animal dander, a cockroach, or dust mites; classified in Class 424, subclass 275.1.

8. Claims 1-11, 14, and 16-42, drawn to a method of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual, wherein the allergen is food allergen; classified in Class 424, subclass 275.1.

9. Claims 1-10, 14, and 16-42, drawn to a method of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual, wherein the allergen is poison ivy; classified in Class 424, subclass 275.1.

10. Claims 1-10, 14, and 16-42, drawn to a method of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual, wherein the allergen is poison oak; classified in Class 424, subclass 275.1.

11. Claims 1-10, 14, and 16-42, drawn to a method of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual, wherein the allergen is poison sumac; classified in Class 424, subclass 275.1.

12. Claims 1-10, 14, and 16-42, drawn to a method of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual, wherein the allergen is a virus; classified in Class 424, subclass 275.1.

13. Claims 1-10, 14, and 16-42, drawn to a method of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual, wherein the allergen is bacteria; classified in Class 424, subclass 275.1.

14. Claims 1-10, 14, and 16-42, drawn to a method of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual, wherein the allergen is protozoa; classified in Class 424, subclass 275.1.

15. Claims 1-10, 14, and 16-42, drawn to a method of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual, wherein the allergen is latex; classified in Class 424, subclass 275.1.

16. Claims 1-8, 10, and 15-42, drawn to a method of modulating an allergic response of an individual comprising delivering a nucleic acid encoding an allergen directly into a lymph node of said individual, wherein the allergen is venom; classified in Class 514, subclass 44.

17. Claims 1-10, 12, and 14-42, drawn to a method of modulating an allergic response of an individual comprising delivering a nucleic acid encoding an allergen directly into a lymph node of said individual, wherein the allergen is pollen; classified in Class 514, subclass 44.

18. Claims 1-8, 10 and 15-42, drawn to a method of modulating an allergic response of an individual comprising delivering a nucleic acid encoding an allergen directly into a lymph node of said individual, wherein the allergen is mold; classified in Class 514, subclass 44.

19. Claims 1-8, 10 and 15-42, drawn to a method of modulating an allergic response of an individual comprising delivering a nucleic acid encoding an allergen directly into a lymph node of said individual carrier, wherein the allergen is an anesthetic; classified in Class 514, subclass 44.

20. Claims 1-8, 10 and 15-42, drawn to a method of modulating an allergic response of an individual comprising delivering a nucleic acid encoding an allergen directly into a lymph node of said individual, wherein the allergen is serum; classified in Class 514, subclass 44.

21. Claims 1-8, 10 and 15-42, drawn to a method of modulating an allergic response of an individual comprising delivering a nucleic acid encoding an allergen directly into a lymph node of said individual wherein the allergen is drugs; classified in Class 514, subclass 44.

22. Claims 1-8, 10, 13, and 15-42, drawn to a method of modulating an allergic response of an individual comprising delivering a nucleic acid encoding an allergen directly into a lymph node of said individual, wherein the allergen is an animals, animal dander, a cockroach, or dust mites; classified in Class 514, subclass 44.

23. Claims 1-8, 10-11 and 15-42, drawn to a method of modulating an allergic response of an individual comprising delivering a nucleic acid encoding an allergen directly into a lymph node of said individual, wherein the allergen is food allergen; classified in Class 514, subclass 44.

24. Claims 1-8, 10, and 15-42, drawn to a method of modulating an allergic response of an individual comprising delivering a nucleic acid encoding an allergen directly into a lymph node of said individual, wherein the allergen is poison ivy; classified in Class 514, subclass 44.

25. Claims 1-8, 10, and 15-42, drawn to a method of modulating an allergic response of an individual comprising delivering a nucleic acid encoding an allergen directly into a lymph node of said individual, wherein the allergen is poison oak; classified in Class 514, subclass 44.

26. Claims 1-8, 10, and 15-42, drawn to a method of modulating an allergic response of an individual comprising delivering a nucleic acid encoding an allergen directly into a lymph node of said individual, wherein the allergen is poison sumac; classified in Class 514, subclass 44.

27. Claims 1-8, 10, and 15-42, drawn to a method of modulating an allergic response of an individual comprising delivering a nucleic acid encoding an allergen directly into a lymph node of said individual, wherein the allergen is a virus; classified in Class 514, subclass 44.

28. Claims 1-8, 10, and 15-42, drawn to a method of modulating an allergic response of an individual comprising delivering a nucleic acid encoding an allergen directly into a lymph node of said individual arrier, wherein the allergen is bacteria; classified in Class 514, subclass 44.

29. Claims 1-8, 10, and 15-42, drawn to a method of modulating an allergic response of an individual comprising delivering a nucleic acid encoding an allergen directly into a lymph node of said individual, wherein the allergen is protozoa; classified in Class 514, subclass 44.

30. Claims 1-8, 10, and 15-42, drawn to a method of modulating an allergic response of an individual comprising delivering a nucleic acid encoding an allergen directly into a lymph node of said individual, wherein the allergen is latex; classified in Class 514, subclass 44.

31. Claims 43-44, drawn to a kit comprising an allergen and a pharmaceutically acceptable carrier, wherein the allergen is venom; classified in Class 435, subclass 810.

32. Claims 43-44, drawn to a kit comprising an allergen and a pharmaceutically acceptable carrier, wherein the allergen is pollen; classified in Class 435, subclass 810.

33. Claims 43-44, drawn to a kit comprising an allergen and a pharmaceutically acceptable carrier, wherein the allergen is mold; classified in Class 435, subclass 810.

34. Claims 43-44, drawn to a kit comprising an allergen and a pharmaceutically acceptable carrier, wherein the allergen is an anesthetic; classified in Class 435, subclass 810.

35. Claims 43-44, drawn to a kit comprising an allergen and a pharmaceutically acceptable carrier, wherein the allergen is serum; classified in Class 435, subclass 810.

36. Claims 43-44, drawn to a kit comprising an allergen and a pharmaceutically acceptable carrier, wherein the allergen is drugs; classified in Class 435, subclass 810.

37. Claims 43-44, drawn to a kit comprising an allergen and a pharmaceutically acceptable carrier, wherein the allergen is an animals, animal dander, a cockroach, or dust mites; classified in Class 435, subclass 810.

38. Claims 43-44, drawn to a kit comprising an allergen and a pharmaceutically acceptable carrier, wherein the allergen is food allergen; classified in Class Class 435, subclass 810

39. Claims 43-44, drawn to a kit comprising an allergen and a pharmaceutically acceptable carrier, wherein the allergen is poison ivy; classified in Class 435, subclass 810.

40. Claims 43-44, drawn to a kit comprising an allergen and a pharmaceutically acceptable carrier, wherein the allergen is poison oak; classified in Class 435, subclass 810.

41. Claims 43-44, drawn to a kit comprising an allergen and a pharmaceutically acceptable carrier, wherein the allergen is poison sumac; classified in Class 435, subclass 810.

42. Claims 43-44, drawn to a kit comprising an allergen and a pharmaceutically acceptable carrier, wherein the allergen is a virus; classified in Class 435, subclass 810.

43. Claims 43-44, drawn to a kit comprising an allergen and a pharmaceutically acceptable carrier, wherein the allergen is bacteria; classified in Class 435, subclass 810.

44. Claims 43-44, drawn to a kit comprising an allergen and a pharmaceutically acceptable carrier, wherein the allergen is protozoa; classified in Class 435, subclass 810.

45. Claims 43-44, drawn to a kit comprising an allergen and a pharmaceutically acceptable carrier, wherein the allergen is latex; classified in Class 435, subclass 810.

46. Claims 43-44, drawn to a kit comprising a nucleic acid encoding an allergen and a pharmaceutically acceptable carrier, wherein the allergen is venom; classified in Class 435, subclass 810.

47. Claims 43-44, drawn to a kit comprising a nucleic acid encoding an allergen and a pharmaceutically acceptable carrier, wherein the allergen is pollen; classified in Class 435, subclass 810.

48. Claims 43-44, drawn to a kit comprising a nucleic acid encoding an allergen and a pharmaceutically acceptable carrier, wherein the allergen is mold; classified in Class 435, subclass 810.

49. Claims 43-44, drawn to a kit comprising a nucleic acid encoding an allergen and a pharmaceutically acceptable carrier, wherein the allergen is an anesthetic; classified in Class 435, subclass 810.

50. Claims 43-44, drawn to a kit comprising a nucleic acid encoding an allergen and a pharmaceutically acceptable carrier, wherein the allergen is serum; classified in Class 435, subclass 810.

51. Claims 43-44, drawn to a kit comprising a nucleic acid encoding an allergen and a pharmaceutically acceptable carrier, wherein the allergen is drugs; classified in Class 435, subclass 810.

52. Claims 43-44, drawn to a kit comprising a nucleic acid encoding an allergen and a pharmaceutically acceptable carrier, wherein the allergen is an animals, animal dander, a cockroach, or dust mites; classified in Class 435, subclass 810.

53. Claims 43-44, drawn to a kit comprising a nucleic acid encoding an allergen and a pharmaceutically acceptable carrier, wherein the allergen is food allergen; classified in Class Class 435, subclass 810

54. Claims 43-44, drawn to a kit comprising a nucleic acid encoding an allergen and a pharmaceutically acceptable carrier, wherein the allergen is poison ivy; classified in Class 435, subclass 810.

55. Claims 43-44, drawn to a kit comprising a nucleic acid encoding an allergen and a pharmaceutically acceptable carrier, wherein the allergen is poison oak; classified in Class 435, subclass 810.

56. Claims 43-44, drawn to a kit comprising a nucleic acid encoding an allergen and a pharmaceutically acceptable carrier, wherein the allergen is poison sumac; classified in Class 435, subclass 810.

57 Claims 43-44, drawn to a kit comprising a nucleic acid encoding an allergen and a pharmaceutically acceptable carrier, wherein the allergen is a virus; classified in Class 435, subclass 810.

58. Claims 43-44, drawn to a kit comprising an allergen and a pharmaceutically acceptable carrier, wherein the allergen is bacteria; classified in Class 435, subclass 810.

59. Claims 43-44, drawn to a kit comprising a nucleic acid encoding an allergen and a pharmaceutically acceptable carrier, wherein the allergen is protozoa; classified in Class 435, subclass 810.

60. Claims 43-44, drawn to a kit comprising a nucleic acid encoding an allergen and a pharmaceutically acceptable carrier, wherein the allergen is latex; classified in Class 435, subclass 810.

4. Groups 31-60 are different products. Kits comprising the allergens as recited differ with respect to the structures and physicochemical properties of the allergens; therefore each product is patentably distinct.

5. Groups 1-30 are different methods. The inventions as grouped in Groups 1-30 are distinct, each from the other, because they represent different inventive endeavors as one does not suggest the other; therefore, each method is patentably distinct.

6. (Groups 31-45 and 1-15, respectively) and (Groups 46-60 and 16-30, respectively) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case the products of groups 31-45 can be used in a materially different process, such as an ELISA, in addition to the methods of modulating recited.

In the instant case the products of groups 46-60 can be used in a materially different process, such as production of the allergen, in addition to the methods of modulating recited.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search, which would not be completely co-extensive. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

8. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

If Groups 3-6, 9-15, 18-21, and 24-30, are elected, applicant is required to elect a specific method of modulating an allergic response of an individual comprising delivering an allergen or a nucleic acid encoding an allergen directly into a lymph node of said individual wherein the allergen is encapsulated with a specific material (e.g. a polymeric material, or a polyanhydride, or a microsphere, etc) with a specific adjuvant (e.g. alum, or BCG, or aluminum hydroxide, etc), and wherein detection is by a specific

reaction (i.e. skin test or controlled allergen exposure) and a specific endpoint property is detected e.g. an increase in specific IgG4, or a decrease in specific IgG4, or, a change in RAST test, etc).

These species are distinct because the methods of modulating an allergic response of an individual comprising delivering an allergen or nucleic acid encoding an allergendirectly into a lymph node of said individual differ with respect to the specific patient population treated, the structure and physiochemical property of the specific allergen or nucleic acid, the specific encapsulating material, the specific adjuvant, the specific detection method and the specific endpoint property; thus each specific method employing a specific allergen in a specific encapsulating agent with a specific adjuvant, and wherein detection is by a specific reaction and a specific endpoint detected represents patentably distinct subject matter. Currently, claims 10, 15, 17, 21, 27, and 31 are generic.

If Groups 7 or 22 are elected, applicant is required to elect a specific method of modulating an allergic response of an individual comprising delivering an allergen or a nucleic acid encoding an allergen directly into a lymph node of said individual wherein the allergen is a specific animal allergen or nucleic acid encoding a specific animal allergen (e.g. dog dander, or cat dander, or cockroaches, etc), and the allergen is encapsulated with a specific material (e.g. a polymeric material, or a polyanhydride, or a microsphere, etc) with a specific adjuvant (e.g. alum, or BCG, or aluminum hydroxide, etc), and wherein detection is by a specific reaction (i.e. skin test or controlled allergen exposure) and a specific endpoint property is detected e.g. an increase in specific IgG4, or a decrease in specific IgG4, or, a change in RAST test, etc).

These species are distinct because the methods of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual differ with respect to the specific patient population treated, the structure and physiochemical property of the specific allergen or the structure of the nucleic acid, the structure and physiochemical property encapsulating material, the structure and physiochemical property adjuvant, the specific detection method and the specific endpoint property; thus each specific method employing a specific allergen, or a specific nucleic acid, in a specific encapsulating agent with a specific adjuvant, and wherein detection is by a specific reaction and a specific

endpoint detected represents patentably distinct subject matter. Currently, claims 10, 13, 15, 17, 21, 27, and 31 are generic.

If Groups 8 or 23 are elected, applicant is required to elect a specific method of modulating an allergic response of an individual comprising delivering an allergen or a nucleic acid encoding an allergen directly into a lymph node of said individual wherein the allergen is a specific food allergen or nucleic acid encoding a specific food allergen (e.g. milk, or fish, or shellfish, or peanuts, etc), and the allergen is encapsulated with a specific material (e.g. a polymeric material, or a polyanhydride, or a microsphere, etc) with a specific adjuvant (e.g. alum, or BCG, or aluminum hydroxide, etc), and wherein detection is by a specific reaction (i.e. skin test or controlled allergen exposure) and a specific endpoint property is detected e.g. an increase in specific IgG4, or a decrease in specific IgG4, or, a change in RAST test, etc).

These species are distinct because the methods of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual differ with respect to the specific patient population treated, the structure and physiochemical property of the specific allergen or the structure of the nucleic acid, the structure and physiochemical property encapsulating material, the structure and physiochemical property adjuvant, the specific detection method and the specific endpoint property; thus each specific method employing a specific allergen, or a specific nucleic acid, in a specific encapsulating agent with a specific adjuvant, and wherein detection is by a specific reaction and a specific endpoint detected represents patentably distinct subject matter. Currently, claims 10-11, 15, 17, 21, 27, and 31 are generic.

If Groups 2 or 17 are elected, applicant is required to elect a specific method of modulating an allergic response of an individual comprising delivering an allergen or a nucleic acid encoding an allergen directly into a lymph node of said individual wherein the allergen is a specific pollen allergen or nucleic acid encoding a specific allergen (e.g. grass pollen or tree pollen or herb pollen), and the allergen is encapsulated with a specific material (e.g. a polymeric material, or a polyanhydride, or a microsphere, etc) with a specific adjuvant (e.g. alum, or BCG, or aluminum hydroxide, etc), and wherein detection is by a specific reaction (i.e. skin test or controlled allergen exposure) and a specific endpoint property is

detected e.g. an increase in specific IgG4, or a decrease in specific IgG4, or, a change in RAST test, etc).

These species are distinct because the methods of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual differ with respect to the specific patient population treated, the structure and physiochemical property of the specific allergen or the structure of the nucleic acid, the structure and physiochemical property encapsulating material, the structure and physiochemical property adjuvant, the specific detection method and the specific endpoint property; thus each specific method employing a specific allergen, or a specific nucleic acid, in a specific encapsulating agent with a specific adjuvant, and wherein detection is by a specific reaction and a specific endpoint detected represents patentably distinct subject matter. Currently, claims 10, 12, 15, 17, 21, 27, and 31 are generic.

If Groups 1 or 16 are elected, applicant is required to elect a specific method of modulating an allergic response of an individual comprising delivering an allergen or a nucleic acid encoding an allergen directly into a lymph node of said individual wherein the allergen is a specific venom allergen or nucleic acid encoding a specific allergen (e.g. bee or wasp or fire ant venom), and the allergen is encapsulated with a specific material (e.g. a polymeric material, or a polyanhydride, or a microsphere, etc) with a specific adjuvant (e.g. alum, or BCG, or aluminum hydroxide, etc), and wherein detection is by a specific reaction (i.e. skin test or controlled allergen exposure) and a specific endpoint property is detected e.g. an increase in specific IgG4, or a decrease in specific IgG4, or, a change in RAST test, etc).

These species are distinct because the methods of modulating an allergic response of an individual comprising delivering an allergen directly into a lymph node of said individual differ with respect to the specific patient population treated, the structure and physiochemical property of the specific allergen or the structure of the nucleic acid, the structure and physiochemical property encapsulating material, the structure and physiochemical property adjuvant, the specific detection method and the specific endpoint property; thus each specific method employing a specific allergen, or a specific nucleic acid, in a specific encapsulating agent with a specific adjuvant, and wherein detection is by a specific reaction and a specific

endpoint detected represents patentably distinct subject matter. Currently, claims 10, 12, 15, 17, 21, 27, and 31 are generic.

If Groups 31 or 46 are elected, applicant is required to elect a kit comprising a specific pollen or a nucleic acid encoding a specific pollen (e.g. bee or wasp or fire ant venom), respectively.

These are distinct because the kits differ with respect to the structures and physiochemical properties of the allergen or nucleic acid encoding said allergen; thus each specific kit employing a specific allergen, or a nucleic acid encoding a specific allergen represents patentably distinct subject matter. Currently, claim 43 is generic.

If Groups 32 or 47 are elected, applicant is required to elect a kit comprising a specific pollen or a nucleic acid encoding a specific pollen (e.g. grass pollen or tree pollen or herb pollen), respectively.

These are distinct because the kits differ with respect to the structures and physiochemical properties of the allergen or nucleic acid encoding said allergen; thus each specific kit employing a specific allergen, or a nucleic acid encoding a specific allergen represents patentably distinct subject matter. Currently, claims 12 and 43 are generic.

If Groups 37 or 52 are elected, applicant is required to elect a kit comprising a specific animal allergen or a nucleic acid encoding a specific animal allergen (e.g. dog dander, or cat dander, or cockroaches, etc), respectively.

These are distinct because the kits differ with respect to the structures and physiochemical properties of the allergen or nucleic acid encoding said allergen; thus each specific kit employing a specific allergen, or a nucleic acid encoding a specific allergen represents patentably distinct subject matter. Currently, claims 13 and 43 are generic.

If Groups 38 or 53 are elected, applicant is required to elect a kit comprising a specific food allergen or a nucleic acid encoding a specific food allergen (e.g. milk, or fish, or shellfish, or peanuts, etc), respectively.

These are distinct because the kits differ with respect to the structures and physiochemical properties of the allergen or nucleic acid encoding said allergen; thus each specific kit employing a specific allergen, or a nucleic acid encoding a specific allergen represents patentably distinct subject matter. Currently, claims 11 and 43 are generic.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is

no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz whose telephone number is (703) 308-8365. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Margaret (Megan) Jamroz, Ph.D.
Patent Examiner
Technology Center 1600
April 1, 2002

Christina Chan
CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1640